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CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 10/646,539 08/22/2003 Jay Douglas Audett ARC3254R1/A5033 9721 27777 03/09/2006 **EXAMINER** PHILIP S. JOHNSON CHANG, VICTOR S JOHNSON & JOHNSON ART UNIT PAPER NUMBER ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 1771

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION		ATTORNEY DOCKET NO.
				EXAMINER
			ART UNIT	PAPER
				030206
			DATE MAILEI) :

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Commissioner for Patents

See attached NOTE.

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NOTE

1. The reply filed on 1/24/2006 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s):

First, for the purpose of clarity, the Examiner would like to repeat (see Office action mailed 10/28/2006, pages 2-5) that in summary, claims 14-16 are mutually elected species of elected II(2), a multilaminate tie layer; III(3), tie layer comprising an antagonist-containing reservoir; and IV(1), release controlling means is the outer layer, and not releasable through base layer. Further, Applicant is reminded (see Office action mailed 10/28/2005, page 5) that because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Second, in an effort to clarify the basis of restriction requirement, the Examiner would like to comment Applicants' newly presented traverses as follows:

1) With respect to Applicant's argument "... The breathable material in claim 2 and claim 3 can be any of the listed materials of claim 3 ... and these breathable materials are closely related ..." (Remarks, page 7, bottom paragraph), the Examiner notes: a) Clearly certain species have distinct and independent structure and/or composition from each other, such as spun-bonded versus coated paper products, and they are not obvious variants. b) It should be noted that the general test as to when claims are restrictable to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a

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second claim recites limitations disclosed only for the second species and not the first. See MPEP 806.04(f).

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- 2) With respect to Applicant's argument "... In claims 1, 7, 8, 12, Applicant uses "comprising", which means that there may or may not be additional features ... there is nothing to preclude the tie layer in these claims to have multiple layers ...", the Examiner notes that while the "comprising" clause of claims 1, 7, 8 and 12 does not preclude additional features, in view of claim 14 does require additional element of multilayered tie layer, as shown in Fig. 2, and also the distinct and independent embodiment shown in Fig. 1, which reads on claims 1, 7, 8 and 12, the Examiner asserts that if multilayered tie layer is an essential limitation of elected species, the lacking of such limitation in claims 1, 7, 8 and 12 renders them either as non-elected species, or not enabling under 35 U.S.C. 112, first paragraph, because it lacks the critical or essential element to the practice of the invention.
- 3) With respect to Applicant's argument "... Original claim 13 comprises a multilaminate tie layer, but is silent on whether there is a drug reservoir. There is nothing to prevent it from including a drug reservoir ..." (Remarks, page 9), the Examiner notes that for same reasons as set forth above, claim 13 lacks the essential element of a drug reservoir, and deemed to be non-elected species.
- 4) With respect to Applicant's argument "... Applicant elected the outer layer regarding a control membrane. But it does not mean that there has to be a control membrane, the election is on a membrane that is on the outer layer ... Applicant should not be forced to include every detail of variations ..." (Remarks, page 9), the Examiner

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repeats that since the original claims recite two distinct and independent species of release controlling means, i.e., "outer layer, and not releasable through base layer" versus "base layer", and they are clearly not variations or equivalent, election requirement is proper.

Third, it is noted that despite Applicants' amendments to claims 14 and 15, cancellation of claims 1-13 and 17, and newly submitted claims 18-30, none of the claims appear to be in accordance of the elected species of "outer layer is an antagonist release rate controlling means and antagonist is not releasable through the base layer". In particular, it should be noted that while new claim 24 recites a limitation "... the outer layer controls the release of a drug that is not delivered to the skin", it does not preclude the same drug being partially released through the base layer. As such, it appears that the directed to non-elected species, and appropriate further amendment is required.

See 37 CFR 1.111. Since the above-mentioned reply appears to be bona fide, applicant is given ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor S Chang

Vas Chang

Examiner Art Unit 1771

3/2/2006